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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,979	03/05/2002	Kohei Fukaya	83363.0002	3628

26021 7590 09/20/2004

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EXAMINER

THOMPSON, MICHAEL M

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/980,979

Applicant(s)

FUKAYA ET AL.

Examiner

Michael M. Thompson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or PTO-1449, they have not been considered.

### ***Claim Rejections - 35 USC § 102/103***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-10, 14-16, 18-19, 21-22, 24, and 27-31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Muni et al.

(5,533,968) or Muni (5,853,408). Both Muni and Muni et al. teach rapid exchange balloon catheters comprising a balloon and a plurality of tubular members wherein the balloon catheter has a first tubular member with the balloon fused concentrically in the vicinity of the distal end wherein the securing is done by thermally fusing the balloon and material miscible with the first tubular member and is made multi-layer through heat bonding or adhesive bonding (abstract, body). Collectively, Muni et al. lists a number of materials and references incorporated by reference wherein the shore hardness, flexural modulus, and therefore melting point is greater for the balloon than the tubular member wherein the balloon is made from a polyimide elastomer and the outermost surface of the tubular member is made of a polyamide elastomer both being polyester elastomer materials. It is the Examiner's position that the materials listed as suitable and incorporated by reference include polyester and polyamide elastomer materials. In the alternative, if Applicant disagrees with the inherent and explicit teachings above it is the Examiner's position that several of the materials are present and disclosed for use in the manufacture of the balloon catheters such as polyester and polyamide elastomers of Muni and Muni et al. and therefore, it would have been obvious to one having ordinary skill in the art, at

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the time of invention to have substituted any of the materials for the tubular portion or balloon portion as disclosed by Muni and Muni et al. since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

6. Claims 11-13, 17, 20, 23, 25-26, and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muni et al. (5,533,968) or Muni (5,853,408). In addressing the limitations directed to the ratio of soft segments, the length of the longitudinal axis of the straight tube, and the blended weight ratios recited by Applicant. The Examiner maintains that at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a soft segment ratio adjusted to be larger than 13 or 14 percent or the length of the longitudinal axis of the straight tube being within a range of 8 mm to 80 mm, or the blended weight ratios of  $(A)/(B) = 98/2$  to  $10/90$  because Applicant has not disclosed that having a soft segment ratio adjusted to be larger than 13 or 14 percent or the length of the longitudinal axis of the straight tube being within a range of 8 mm to 80 mm, or the blended weight ratios of  $(A)/(B) = 98/2$  to  $10/90$  provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants invention to perform equally well with a soft segment ratio adjusted to be larger than 12 percent or the length of the longitudinal axis of the straight tube being within a range of 5 mm to 90 mm, or the blended weight ratios of  $(A)/(B) = 95/5$  to  $5/95$  because each range or percentile would perform the same function of the balloon catheter for angioplasty.

***Response to Arguments***

7. Applicant's arguments, see arguments, filed 06-01-2004, with respect to the objection of multiple dependency have been fully considered and are persuasive. The objection of 03-01-2004 has been withdrawn. However, it is the Examiner's position that the prior art is still applicable. Applicant should note that the Examiner has recited that the limitations related to the mechanical properties are inherent in the materials taught by both Muni references collectively. The Examiner has made an inherent *prima facie* case relying upon the materials disclose as suitable materials for the catheter device of both Muni references. The Examiner is relying upon the inherent properties of the materials disclosed as suitable for construction of the catheter devices taught by both Muni references. Applicants own dependency shows the use of polyester and polyamide used to obtain these properties. Ex parte Chicago rawhide MFG. Co., appears to speak specifically to *making changes in the reference device*. The Examiner is not making changes to the reference device, the Examiner is merely reciting the suitable materials or combinations thereof that have been recited as acceptable materials for construction and their inherent properties.

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### Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Nick Lucchesi, can be reached on (703) 308-2698. The official fax phone number for all submissions to the organization where this application or proceeding is assigned is (703) 872-9306.

Michael M. Thompson

Patent Examiner

  
NICHOLAS D. LUCCHESI  
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TECHNOLOGY CENTER 3700

MT 

September 16, 2004